



Patent
Attorney's Docket No. 003300-790

1647
#12
7/22/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
)
Åsa BERGLUND) Group Art Unit: 1647
)
Application No.: 09/869,269) Examiner: Jegatheesan Seharaseyon
)
Filed: July 11, 2001) Confirmation No.: 2429
)
For: MODIFICATION OF INTERFERON)
ALPHA PRODUCTION)

AMENDMENT/REPLY TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RECEIVED

JUL 08 2003

Sir:

TECH CENTER 1600/2900

Enclosed is a reply for the above-identified patent application.

- ☐ A Petition for Extension of Time is also enclosed.
- ☐ A Terminal Disclaimer and the ☐ \$55.00 (2814) ☐ \$110.00 (1814) fee due under 37 C.F.R. § 1.20(d) are also enclosed.
- ☐ Also enclosed is/are _____
- ☐ Small entity status is hereby claimed.
- ☐ Applicant(s) requests continued examination under 37 C.F.R. § 1.114 and enclose the ☐ \$375.00 (2801) ☐ \$750.00 (1801) fee due under 37 C.F.R. § 1.17(e).
- ☐ Applicant(s) previously submitted __, on __, for which continued examination is requested.
- ☐ Applicant(s) requests suspension of action by the Office until at least __, which does not exceed three months from the filing of this RCE, in accordance with 37 C.F.R. § 1.103(c). The required fee under 37 C.F.R. § 1.17(i) is enclosed.
- ☐ A Request for Entry and Consideration of Submission under 37 C.F.R. § 1.129(a) (1809/2809) is also enclosed.
- ☒ No additional claim fee is required.

☐ An additional claim fee is required, and is calculated as shown below:

AMENDED CLAIMS					
	NO. OF CLAIMS	HIGHEST NO. OF CLAIMS PREVIOUSLY PAID FOR	EXTRA CLAIMS	RATE	ADD'L FEE
Total Claims		MINUS =		× \$18.00 (1202) =	
Independent Claims		MINUS =		× \$84.00 (1201) =	
If Amendment adds multiple dependent claims, add \$280.00 (1203)					
Total Amendment Fee					
If small entity status is claimed, subtract 50% of Total Amendment Fee					
TOTAL ADDITIONAL FEE DUE FOR THIS AMENDMENT					

☐ A claim fee in the amount of \$_____ is enclosed.

☐ Charge \$_____ to Deposit Account No. 02-4800.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17, 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: July 3, 2003

By: Deborah H. Yellin
Deborah H. Yellin
Registration No. 45,904

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620



Patent
Attorney's Docket No. 003300-790

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
)
Åsa BERGLUND) Group Art Unit: 1647
)
Application No.: 09/869,269) Examiner: Jegatheesan Seharaseyon
)
Filed: July 11, 2001) Confirmation No.: 2429
)
For: MODIFICATION OF INTERFERON)
ALPHA PRODUCTION)

RESPONSE TO RESTRICTION REQUIREMENT

RECEIVED

JUL 08 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TECH CENTER 1600/2900

Sir:

In complete response to the Restriction Requirement [species election requirement] set forth in the Official Action mailed on April 7, 2003 (Paper No. 11), Applicants hereby elect with traverse the following species, (as recited specifically generic claims 8 and 20):

Species (a)(1) xanthine and its derivatives;

Species (b) (3) cyclic amides;

and a combination of species (a)(1) and (b)(3).

Applicants reserve the right to pursue any subject matter not elected herein, at a later time as necessary.

Applicants respectfully traverse the species election requirement for the following reasons.

Applicants note that the independent process claim of the present invention, claim 1, recites a process for producing α -interferon comprising (i) inducing human leukocytes by means of a virus and (ii) treating the leukocytes with an enhancing agent. Specifically, claim 1 recites:

Claim 1. (Original) A process for the production of α -interferon comprising the steps:

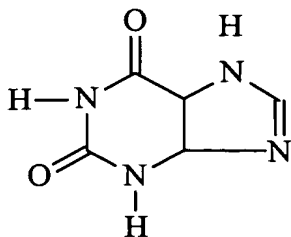
- i) inducing of human leukocytes by means of a virus,
 - ii) treating the leukocytes with an enhancing agent selected from
 - a) xanthine, pyrimidinol, pyrimidinone, theophylline, theobromine, enprophylline, hypoxanthine, 8-phenyltheophylline, 2-amino-5-bromo-6-methylpyrimidinol, 2-amino-6-methyl-4-pyrimidinol and thymine;
 - b) an organic solvent selected from the group consisting of non-aromatic ketones, aliphatic or cyclic amides, alkylated aliphatic or cyclic urea derivatives and aliphatic or cyclic sulfoxides;
- or a combination of the compounds from a) with an organic solvent from b).

Applicants emphasize that claim 1, the independent claim, recites an enhancing agent in element (ii) that is selected from element (a) (organic compounds); element (b) (organic solvents); and a combination of (a) (organic compounds) and (b) (organic

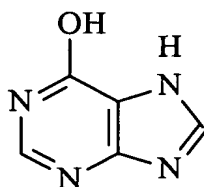
solvents). Thus, both the organic compounds of element (ii)(a) and the organic solvents from element (ii)(b), or a combination thereof, may act as the enhancing agent according to the invention. However, the language of the outstanding Office Action requires that an enhancing agent and an organic solvent be elected, and treats them as separate (*see* Detailed Action, page 2). However, as noted above, the organic solvent is an enhancing agent, as recited in claim 1. Thus, the present species election appears to be inappropriate, with regard to what is claimed.

Thus, Applicants have elected herein an organic compound from element (ii)(a) of claim 1 and an organic solvent from element (ii)(b) of claim 1, as well as a combination of (a) and (b) as recited in claim 1. Further, Applicants request rejoinder of all of the species of organic compounds of claim 1(ii)(a). The outstanding Office Action states that the species are structurally dissimilar. Applicants submit that this is not the case, as the species form a single inventive concept under PCT Rule 13.1, both structurally and functionally. Applicants also request that the alkylated aliphatic or cyclic urea derivatives of claim 1(ii)(b), including tetramethylurea and 1,3-dimethyl-2-imidazolidinone, be examined at this time.

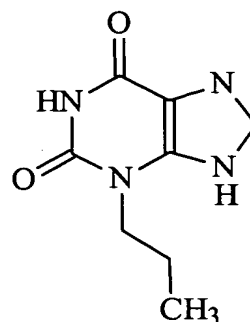
Specifically, The following group of compounds, xanthine and its derivatives (species (a)(1)), are as follows, and constitute one species:



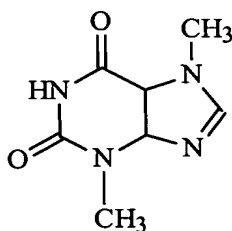
xanthine



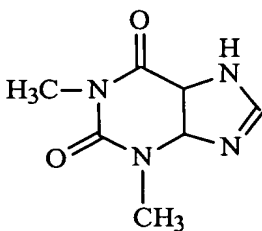
hypoxanthine



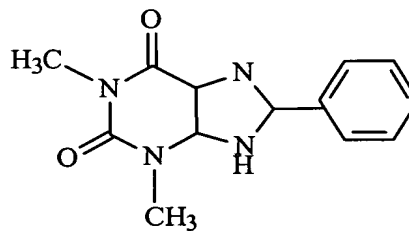
enprophylline



theobromine



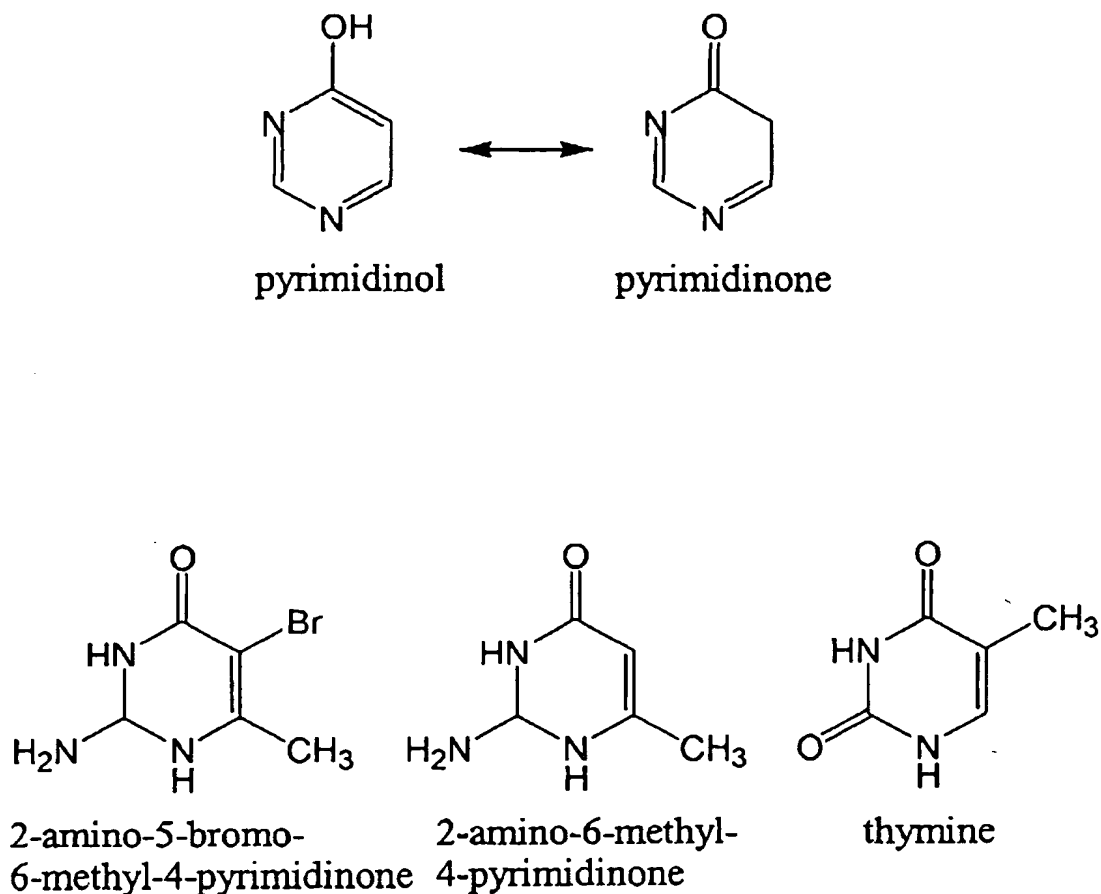
theophylline



8-phenyltheophylline

Applicants submit that all of the species of claim 1(ii)(a) are both structurally and functionally related. Specifically, they all share the common function of acting as an enhancing group for the claimed process and are structurally related, in that they share the same pyrimidine ring structure as xanthine and its derivatives, substituted with a hydroxy/keto group. Applicants further emphasize that pyrimidinol and pyrimidinone are

tautomers, and so are the same compound alternating between different forms. For example, Applicants refer to the structures below.

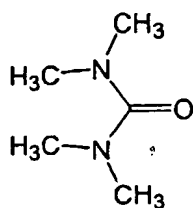


Applicants also respectfully request the rejoinder of all of the species of organic solvents of claim 1(ii)(b), as the species form a single inventive concept under PCT Rule 13.1, both structurally and functionally. All of the species of organic solvents share the common function of the claimed invention and are structurally related. Specifically, the cyclic solvents of claim 1(ii)(b) have structures that are closely related to that of the

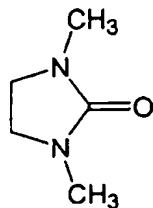
xanthine derivatives, including one or two nitrogen atoms in the cyclic backbone. The aliphatic organic solvents are structurally highly similar to the corresponding cyclic compounds, which is evident from the structures set forth below. As is evident, all the compounds share the same central keto structure, favorably with one or two adjacent nitrogen atoms.

Further, the central keto structure is a recurring theme also for the compounds of claim 1(ii)(a), because they either are built on a xanthine structure, comprising a pyrimidinone group, or are built on a pyrimidinone structure, where the keto/enol group is a central motif, favorably with one or two adjacent nitrogen atoms.

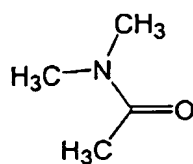
If the Examiner will not rejoin all of the organic solvent species of claim 1(ii)(b) at this time, Applicants respectfully request that at least the aliphatic and cyclic amides of claim 1(ii)(b) should be examined together. The aliphatic and cyclic amides share both functional and structural properties, as seen with the structures for N,N-dimethylacetamide and 2-pyrrolidinone, N-methyl-2-pyrrolidinone, and N-ethyl-2-pyrrolidinone. In this respect, Applicants also request the rejoinder of the alkylated aliphatic or cyclic urea derivatives.



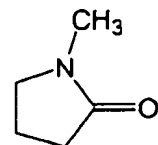
tetramethylurea



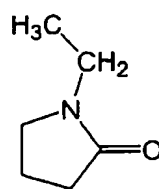
1,3-dimethyl-
imidazolidinone



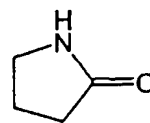
N,N-dimethyl-
acetamide



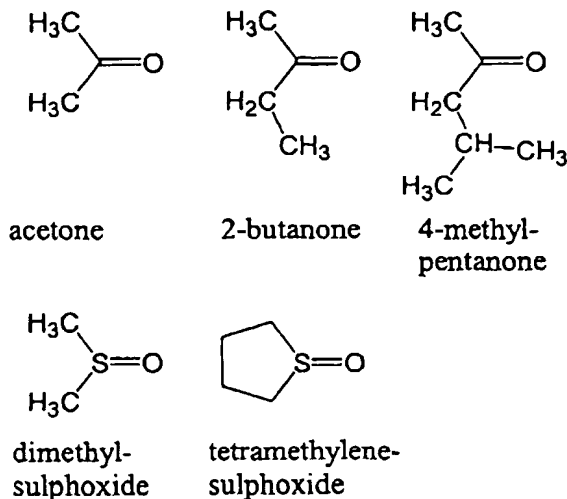
N-methyl-
pyrrolidinone



N-ethyl-
pyrrolidinone



2-pyrrolidinone




Accordingly, for at least all of the reasons set forth above, withdrawal of the requirement for restriction [species election requirement] is requested and believed to be in order.

In the event that there are any questions relating to this Reply to Restriction Requirement, or the application in general, it would be appreciate if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: July 3, 2003

By: 
Deborah H. Yellin
Registration No. 45,904

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620